

**REMARKS/ARGUMENTS**

Applicants thank the Examiner for conducting a telephone interview with the undersigned on December 17, 2004 at which the outstanding office action was discussed. Specifically, the Examiner said that although he found the disclosed utility of forensic analysis of the claimed polymorphisms credible, he was questioning whether the utility was specific and substantial. More particularly, the Examiner questioned whether the claimed polymorphisms could indeed be used to identify different individuals by, for example, the FBI. Applicants pointed out that Table 1 at p. 30 of the specification shows the polymorphic profile in ten individuals at the claimed polymorphic sites (see explanation of Table 1 at p. 8 of the specification). Applicants also pointed out that the polymorphic profile for each individual was different indicating that analysis of the claimed polymorphic sites can be used to distinguish different individuals. The Examiner said that this evidence may be persuasive on further consideration.

The Examiner then said that the numbering in Table 1 (as originally filed) was displaced by one from the numbering of polymorphic sites in the present claims. This discrepancy was explained in a previous response filed June 18, 2001 and a corrected Table 1 was supplied. In brief, the discrepancy arose because the polymorphic sites in the original Table 1 were numbered in accordance with the first nucleotide being assigned the number zero, rather than 1 as is conventional.

Applicants now turn to the specific comments in the office action.

Claims 1, 3-10 and 15-32 stand rejected under 35 USC 101 for alleged lack of utility. In the previous response, applicants pointed out that the application discloses a credible, substantial and specific utility for the claimed polymorphic sites in forensic analysis. In brief, the utility is credible because it involves standard techniques of molecular biology and statistical analysis. The utility is specific because there are relatively few mitochondrial polymorphisms compared with genomic polymorphisms and mitochondrial polymorphisms offer advantages that they can be detected in small amounts of DNA (due to the presence of large numbers of

mitochondria per cell). The utility is substantial because *inter alia* the FBI is using mitochondrial polymorphisms analysis as part of its criminal investigations.

In response, the Examiner alleges that in the absence of factual support, applicants have not provided any reasoning or evidence that polymorphism containing sequences as presently claimed would expected to be of the type usable for identification, and that in consequence no substantial utility has been set forth. The Examiner also alleges that generic identification language lacks specificity as to identifying any specific individual. The Examiner further alleges that no relationship has been set forth between testing conducted by the FBI, and the present polymorphism. The Examiner acknowledges that a utility does not have to be unique, and also that the forensic usage of mitochondrial polymorphisms is credible. This rejection is respectfully traversed.

First, the Examiner appears to be incorrectly transferring the burden of proof to applicants.

As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented *must* be taken as sufficient to satisfy the utility requirement of §101 for the entire claimed subject matter *unless* there is a reason for one skilled in the art to question the objective truth of the statement of utility or scope.

*In re Langer*, 183 USPQ 288, 297 (CCPA 1974) (emphasis in original).

Here, the Examiner has not provided any reasons that the FBI could not use the claimed polymorphic sites in forensic analysis; rather, the Examiner appears to be suggesting that applicants need to provide additional evidence that the FBI can so use the sites. Such a position incorrectly transfers the burden of proof to applicant.

In any event, at the interview, the Examiner clarified that the type of evidence he was looking for was evidence that the claimed polymorphic sites could be used to distinguish one individual from another. As was pointed out at the interview, such evidence is provided by

Table 1. The Examiner is requested to refer to the revised form of Table 1 submitted June 18, 2001. The Table shows the polymorphic profile of ten individuals (HA001 to YR0119) at the polymorphic sites specified in the present claims. It can be seen that the polymorphic profiles of each of the ten individuals differ at numerous positions from one another. Accordingly, if one determined the polymorphic profile of a mitochondrial DNA sample from the scene of a crime at the claimed polymorphic sites, and compared this with the profile of any of the individuals in Table 1 one could determine whether the profile of the individual matched that of the sample. Because the individuals in Table 1 were not selected because they had any particular profile, one would expect a similar result for any other individual. The ability to determine a match between a DNA sample at the scene of a crime, and other individuals would undoubtedly be useful to the FBI. Thus, there is evidence confirming that the disclosed utility is substantial and no evidence to the contrary.

The Examiner also alludes to the disclosed utility not being specific to the identification of any specific individual. However, polymorphic sites that could only identify a specific individual would have very little utility because the odds of any single person being involved in a crime or other situation in which forensic analysis are useful are not high. The specificity of the disclosed utility is conferred not by the claimed polymorphisms only being useful to analyze a specific individual but rather in that they are part of a small subset of all polymorphisms that are particularly useful for forensic analysis due to the ability to detect them in smaller samples of DNA, as discussed above and in the previous response.

For these reasons, it is submitted that the Examiner has not met his burden of proving that the disclosed utility is not specific, substantial and credible, and that the rejection should be withdrawn.


The claims also stand rejected under 35 USC 112, first paragraph on the basis that the specification does not teach how to use the claimed polymorphisms. The substance of the rejection appears to be the same as under 35 USC 101 and applicants respond in the same manner.

Appl. No. 08/856,376  
Amdt. dated December 22, 2004  
Amendment under 37 CFR 1.116 Expedited Procedure  
Examining Group

PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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